

APPLICATION FOR UNITED STATES LETTERS PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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Title: GUM BASED CHEWING PRODUCT AND PROCESS FOR PREPARING THE
SAME

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RELATED APPLICATION

- [01] This application claims priority to Indian Application No. 543/CAL/02, filed September 17, 2002, entitled "Gum Based Chewing Product," which is incorporated herein by reference in its entirety.

FIELD OF INVENTION

- [02] The present invention relates to a gum based product and a process for manufacturing the same. More particularly the invention relates to a gum based product with a synthetic or natural betel nut source, especially a chewing / bubble gum containing an alkaloid-like composition, such as nicotine or other such alkaloids like caffeine, theine etc. from natural or synthetic origin for its source, with or without taste enhancers and a process for preparing the same.

BACKGROUND

- [03] Tobacco flavored chewing gum or chewing gum containing tobacco, which simulates chewing tobacco are known in the art and have been described in US patent nos. 3,877,468; 5,488,976; 4,317,837; 4,802,498; 4,093,752; 3,845,217; 865,026 and 904,521.
- [04] This tobacco-flavored chewing gum is usually recommended for smokers as a substitute for smoking tobacco. US patent 3,877,468 and 5,488,962 disclosed chewing gum having variable amounts of nicotine. US patent 4,317,837 and 4,802,498 describe chewing gum wherein tobacco rather than nicotine is added to chewing gum. US 4,093,752 employs tobacco flavorings such as 2, 4, 6-triisobutyl 1-1, 3, 5-trioxane and US 3,845,217 employs buffered nicotine in chewing gum. Further mixtures of tobacco and wax are used in US patent nos. 865,026 and 904,521. The tobacco flavorings may be employed along with non-sweet taste or flavorings such as salt, pepper, sour, bitter, meaty, with or without sweetness as desired.
- [05] In the tropical Asian countries, chewing betel nut and tobacco in the form of areca quid is quite popular. This type of Areca quid mainly consists of Areca nut (betel nut), lime paste (in India known as chuna), a resinous extract from the matrix of

Acacia tree (in India known as Kattha or catechu). All these are spread over betel leaf and the whole quid is consumed along with the betel leaf, which is known as 'pan' in India.

[06] The consumption of betel nut and tobacco together in the form of Areca quid has many disadvantages like:

- i. it generates a bright thick red colored fluid which mixes with the saliva and has to be expectorated and causes pollution of the environment;
- ii. this type of Areca tobacco mixture mostly contains alkaline lime, which in long use could result in oral cancer; and
- iii. long use of such Areca / tobacco mixtures cause contraction of oral tissue which results in incapability of opening the mouth fully.

[07] To overcome these Indian Patent No. 187110 granted to the applicant herein describes use of quimam and betel nut in chewing gum.

SUMMARY OF INVENTION

[08] The present invention is an improvement over Indian Patent No. 187110. It delivers nicotine source, prepared in a particular method, at a level of 1mg to 12.6 mg per chewing gum and has a better mixing capacity with the gum base. Moreover as the per chewing gum dose of nicotine is limited and can be chewed for a longer time a sustained effect is achieved though the overall consumption of nicotine is less. Moreover the product smoothness is much higher as well as saliva generation in the present chewing gum is much lesser. Further the incorporation of taste enhancers selected from catechu and or lime along with the betel nut and nicotine source provides a better overall taste and chewing property along with improved product smoothness and feel attributes. It provides further a longer lingering effect causing reduction in intake of nicotine per day.

[09] The present invention relates to a gum based product comprising:

- from 12-35% by weight of a gum base in the form of dough;
- from 0.-7.0% by weight of a plasticizer;
- from 0.05 to 5.75% by weight of a nicotine source;

from 35-65% by weight of a filler;
1.5-9% by weight of betel nut powder having average particle size of between 45 μ m to 710 μ m;
0.1 to 4.5% by weight of one or more flavoring agent;
said chewing gum based product being in the form of gum pieces adapted to deliver 1.0 to 12.6 mg of nicotine per piece.

[10] According to further aspect of the present invention there is provided a process for preparing the gum based product along with nicotine source comprising:

- i) providing a mixture comprising 12-35% by weight of chewing gum base, 0-7.0% by weight of plasticizer, 3-30% by weight of dough forming medium, a filler, 1.5-9% by weight of betel nut powder having average particle size of between 45 μ m to 710 μ m;
- ii) heating the mixture to a temperature between 45°C to 65°C to soften the gum base and form a dough;
- iii) adding from 0.05 to 5.75% by weight of nicotine source to the dough;
- iv) adding 0.1 to 4.5% by weight of one or more flavoring agent such as herein described followed by addition of a further amount of filler and mixing the mass thoroughly to obtain the chewing gum; and
- v) converting the said mass into chewing gum pieces containing nicotine at a level of 1.0 to 12.6 mg per piece.

[11] According to another aspect of the present invention there is provided a gum based product with taste enhancers comprising:

12-35% by weight of a gum base in the form of dough;
0.-7.0% by weight of a plasticizer;
0.05 to 5.75% by weight of a nicotine source;
35-65% by weight of a filler;
0.1 to 3.7% of taste enhancer selected from catechu and or lime;
1.5-9% by weight of betel nut powder having average particle size of between 45 μ m to 710 μ m;

0.1 to 4.5% by weight of one or more flavoring agent;
said chewing gum based product being in the form of gum pieces adapted to deliver 1.0 to 12.6 mg of nicotine per piece.

[12] According to further aspect of the present invention there is provided a process for preparing the gum based product with taste enhancers along with nicotine source comprising:

- i) providing a mixture comprising 12-35% by weight of chewing gum base, 0-7.0% by weight of plasticizer, 3-30% by weight of dough forming medium, a filler, 1.5-9% by weight of betel nut powder having average particle size of between 45 μ m to 710 μ m, and 0.1 to 3.7% of taste enhancer selected from catechu and or lime;
- ii) heating the mixture to a temperature between 45°C to 65°C to soften the gum base and form a dough;
- iii) adding from 0.05 to 5.75% by weight of nicotine source to the dough;
- iv) adding 0.1 to 4.5% by weight of one or more flavoring agent such as herein described followed by addition of a further amount of filler and mixing the mass thoroughly to obtain the chewing gum;
- v) converting the said mass into chewing gum pieces containing nicotine at a level of 1.0 to 12.6 mg per piece.

[13] The gum used for the purpose of the present invention is the one for which the active components are as above and is selected from chewing gum, bubble gum and other gums.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[14] The invention is described with specific reference to chewing gum although other gums may be used.

[15] The present invention provides a betel nut containing chewing gum with nicotine source with or without taste enhancers like catechu and or lime, which has a lingering effect of the nicotine though the per chewing gum consumption of

nicotine is limited. It also provides product smoothness. The saliva generation associated with the betel nut chewing gum with nicotine source of the present invention is also less than intake of areca quid and chewing gum with quimam. It provides all the attributes of intake of areca quid but without the ill effects of increased saliva formation and staining of the teeth and mouth. The present invention with taste enhancers provides added attributes of better taste and chewing property to the product over those without such taste enhancers.

[16] According to a preferred aspect the said betel-nut chewing gum with or without taste enhancers along with nicotine source further comprises from 0.02 to 7.5% by weight of sweetening agent wherein the sweetening agent is selected from the group consisting of Aspartame, mannitol, powdered sugar and the like.

[17] The said chewing gum preferably comprises:

25-34% by weight of a chewing gum base in the form of dough;

1-1.5% by weight of plasticizer;

3 to 3.5% by weight of nicotine source;

32.9-55% by weight of filler;

4-6% by weight of betel nut powder of average particle size ranging from 45 μ m to 710 μ m;

0.5 to 3.0% of catechu or 0.1 - 0.7% lime as taste enhancer;

0.1-6% by weight of sweetening agent;

0.1 to 1.5% by weight of peppermint source and/or any other flavoring agent such as herein described;

said chewing gum having shaped of sizes adapted to deliver 1.0 to 7 mg of nicotine per piece of chewing gum.

[18] The amount of taste enhancer when present is 0.1 to 0.7%. The said taste enhancer is selected from catechu and or lime. Amount of catechu when present as taste enhancer ranges between 0.5 to 3% while that of lime is from 0.1 to 0.7%. According to most preferred aspect both catechu and lime are present as taste enhancers in the gum based chewing gum with nicotine source.

- [19] The plasticizer in the said product with nicotine source is propylene glycol or glycerin and the dough forming medium is selected from the group consisting of liquid sorbitol, maltitol syrup, liquid glucose and like while the filler in the said product is powdered D-Sorbitol or powdered sugar. The use of plasticizer may be optional in view of the use of both the taste enhancers.
- [20] Thus according to most preferred aspect the gum based product comprises:
- 25-34% by weight of a chewing gum base in the form of dough;
 - 3 to 3.5% by weight of nicotine source;
 - 32.9-55% by weight of filler;
 - 4-6% by weight of betel nut powder of average particle size ranging from 45 μ m to 710 μ m;
 - 0.5 to 3.0% of catechu and 0.1 to 0.7% lime as taste enhancer;
 - 0.1-6% by weight of sweetening agent;
 - 0.1 to 1.5% by weight of peppermint source and/or any other flavoring agent such as herein described;
 - said chewing gum having shaped of sizes adapted to deliver 1.0 to 7 mg of nicotine per piece of chewing gum.
- [21] The flavoring agent in the product is selected from the group consisting of germanium oil, cardamom flavor, saffron flavor, clove oil, cinnamon flavor, tobacco flavor A, tobacco flavor B, tobacco flavor C, cardamom powder, and menthol powder or mentha piperita oil as peppermint source.
- [22] The said flavoring agents are added in the following proportions:

| <u>Flavoring agent</u> | <u>Range (% by wt)</u> |
|------------------------|------------------------|
| Germanium oil | 0.7-0.9 |
| Cardamom flavor | 2-3 |
| Saffron flavor | 0.15-0.35 |

| | |
|-------------------|-----------|
| Clove oil | 0.15-0.35 |
| Cinnamon flavor | 0.5-0.6 |
| Tobacco flavor A | 0.5-3.5 |
| Tobacco flavor B | 1.0-4.5 |
| Tobacco flavor C | 0.5- 1.5 |
| Cardamom powder | 0.5-1.5 |
| Peppermint source | 0.5-2.0 |

[23] The preferred range of one or more flavoring agent added is as follows:

| <u>Flavoring agent</u> | <u>Preferred range (% by wt)</u> |
|------------------------|----------------------------------|
| Germanium oil | 0.75 –0.85 |
| Cardamom flavor | 2.0 –3.0 |
| Saffron flavor | 0.2 – 0.3 |
| Clove oil | 0.2 –0.3 |
| Cinnamon flavor | 0.5 –0.6 |
| Tobacco flavor A | 2.2 – 3.0 |
| Tobacco flavor B | 3.0 – 3.5 |
| Tobacco flavor C | 0.8 – 1.2 |
| Cardamom powder | 0.8 – 1.2 |
| Peppermint source | 0.8 – 1.2 |

[24] The nicotine source used in the present invention may be prepared by conventional methods. According to a preferred aspect of the present invention the process for preparing the nicotine source to be used in the said gum based product comprises:

filling up fine scrap of tobacco in a metallic column;
 passing steam through the column and collecting the condensed extract of tobacco at the bottom of the column;
 continuing the cycle till the extraction is complete;
 passing the collected extract through 'falling film evaporator' to concentrate the extract to 35% of the initial tobacco weight;

cooling to room temperature and adding required flavoring agents as described herein.

[25] The process for preparing betel-nut containing chewing gum with nicotine source with or without taste enhancers like catechu and or lime as described herein further comprising of gradually adding 0.02-7.5% by weight of sweetening agent selected from the group consisting of Aspartame, mannitol powdered sugar and the like. The preferred aspect of the said process for preparing chewing gum comprises:

- i) providing a mixture comprising 25-34% by weight of chewing gum base, 0-1.5% by weight of plasticizer, 6-22% by weight of dough forming medium, a filler, from 0.5 to 3% of catechu or 0.1-0.7% of lime as taste enhancer, 4-6% by weight of betel nut powder of average particle size ranging from 45 μ m to 710 μ m, 0.1-6% by weight of sweetening agent;
- ii) heating to a temperature between 45°C to 60°C to soften the gum base to form a dough;
- iii) adding 3 to 3.5% by weight of nicotine source of a type obtained by a process such as herein described to the dough;
- iv) adding 0.1 to 1.5% by weight of peppermint source or any other flavoring agent such as herein described followed by addition of further amount of filler and mixing it thoroughly to obtain the chewing gum;
- v) converting the said mass into chewing gum pieces so as to deliver 1.0 to 7mg of nicotine per piece of chewing gum.

[26] Preferably both the taste enhancers may be used in the said process and in such process the plasticizer is not used. Thus the said process comprises:

- i) providing a mixture comprising 25-34% by weight of chewing gum base, 6-22% by weight of dough forming medium, a filler, 0.5 to 3.0% of catechu and 0.1 to 0.7% of lime as taste enhancers, 4-6% by weight of betel nut powder of average particle size ranging from 45 μ m to 710 μ m, 0.1-6% by weight of sweetening agent;

- ii) heating to a temperature between 45°C to 60°C to soften the gum base to form a dough;
- iii) adding 3 to 3.5% by weight of nicotine source of a type obtained by a process such as herein described to the dough;
- iv) adding 0.1 to 1.5% by weight of peppermint source or any other flavoring agent such as herein described followed by addition of further amount of filler and mixing it thoroughly to obtain the chewing gum; and converting the said mass into chewing gum pieces so as to deliver 1.0 to 7 mg of nicotine per piece of chewing gum.

[27] After addition of the nicotine source the mass is preferably reheated for uniform mixing of the nicotine source in the dough.

[28] The filler is incorporated in the mix at a level of between 15-80% of the total filler to be present in the chewing gum and at a subsequent stage adding the balance filler in an amount of between 20-85%.

[29] The formation of the said chewing gum pieces is preferably done by spreading the said chewing gum mass obtained at the step (iv) of the process of preparation in the form of a sheet of uniform thickness and cut into shaped pieces of sizes adapted to deliver 1.0 to 12.6 mg, preferably 1-7mg of nicotine per dose of chewing gum.

[30] The dough forming medium used in the said process is selected from the group consisting of liquid sorbitol, maltitol syrup, liquid glucose and the like, while the filler used is powdered D-Sorbitol, powdered sugar and the plasticizer used is propylene glycol or glycerin.

[31] The flavoring agent used in the nicotine source is selected from the group consisting of germanium oil, cardamom flavor, saffron flavor, clove oil, cinnamon flavor, tobacco flavor A, tobacco flavor B, tobacco flavor C, cardamom powder, menthol powder or mentha piperita oil as peppermint source.

[32] The one or more flavoring agent used are added in the following proportions:

| <u>Flavoring agent</u> | <u>Range (% by wt)</u> |
|------------------------|------------------------|
| Germanium oil | 0.7-0.9 |
| Cardamom flavor | 2.0-3.0 |
| Saffron flavor | 0.15-0.35 |
| Clove oil | 0.15-0.35 |
| Cinnamon flavor | 0.5-0.6 |
| Tobacco flavor A | 0.5-3.5 |
| Tobacco flavor B | 1.0-4.5 |
| Tobacco flavor C | 0.5- 1.5 |
| Cardamom powder | 0.5-1.5 |
| Peppermint source | 0.5-2.0 |

[33] The preferred range of one or more flavoring agent used is as follows:

| <u>Flavoring agent</u> | <u>Preferred range (% by wt)</u> |
|------------------------|----------------------------------|
| Germanium oil | 0.75 – 0.85 |
| Cardamom flavor | 2.0 – 3.0 |
| Saffron flavor | 0.2 – 0.3 |
| Clove oil | 0.2 – 0.3 |
| Cinnamon flavor | 0.5 – 0.6 |
| Tobacco flavor A | 2.2 – 3.0 |
| Tobacco flavor B | 3.0 – 3.5 |
| Tobacco flavor C | 0.8 – 1.2 |
| Cardamom powder | 0.8 – 1.2 |
| Peppermint source | 0.8 – 1.2 |

[34] The invention shall now be described with reference to non restrictive exemplary illustrations

[35] Example 1

CHEWING GUM COMPOSITION:

The composition of chewing gum is as follows:

Gum base 30% by weight

Plasticizer (propylene glycol or glycerin) 1.0% by weight

Dough forming medium (liquid sorbitol 70%) 13.0% by weight

Nicotine source 3.2% by weight

Filler (powdered D-Sorbitol) 47.7% by weight

Betel nut powder (45 μ m to 710 μ m) 4.5% by weight

Sweetening agent (Aspartame or any other material providing required sweetness)
0.1% by weight

Peppermint 0.5% by weight and/or any other flavoring agents and mixing the composition thoroughly.

PREPARATION OF CHEWING GUM:

[36] To prepare the chewing gum of this composition the following process is followed:

- i) mixing chewing gum base, plasticizer, dough forming medium, a portion of filler, betel nut powder and sweetening agent;
- ii) heating the above mixture at 45°C to soften the gum base to form a dough;
- iii) adding the nicotine source prepared by the method as described above to the dough and reheating the dough for uniform mixing of the nicotine source in the dough;
- iv) adding peppermint and any other flavoring agent and mixing thoroughly;
- v) gradually adding the remaining portion of the filler to obtain the tobacco chewing gum mass;

- vi) spreading the said chewing gum mass in the form of a sheet of uniform thickness and cut into rectangular or any other shaped pieces. The cut pieces are wrapped in wax paper / aluminum foil for airtight packing. The nicotine source used will deliver 1.0 mg to 12.6 mg of nicotine per dose i.e. per piece of chewing gum.

[37] Example 2

COMPOSITION OF CHEWING GUM:

The composition of chewing gum is as follows:

Gum base 32.5% by weight

Plasticizer (propylene glycol or glycerin) 1.0% by weight

Dough forming medium (Maltitol syrup) 6.5% by weight

Nicotine source 3.2% by weight

Filler (powdered D-Sorbitol) 50.8% by weight

Betel nut powder (45 μ m to 710 μ m) 5.0% by weight

Peppermint 1.0% by weight and / or any other flavoring agents and mixing the composition thoroughly.

PREPARATION OF CHEWING GUM:

[38] To prepare the chewing of this composition the following process is followed:

- i) mixing chewing gum base, plasticizer, dough forming medium, a portion of filler and betel nut powder;
- ii) heating the above mixture at 55°C to soften the gum base to form a dough;
- iii) adding the nicotine source prepared by the method as described above to the dough and reheating the dough for uniform mixing of the nicotine source in the dough;
- iv) adding peppermint and any other flavoring agent and mixing thoroughly;

- v) gradually adding the remaining portion of filler to obtain the chewing gum mass;
- vi) spreading the said chewing gum mass in the form of a sheet of uniform thickness and cut into rectangular or any other shaped pieces. The cut pieces are wrapped in wax paper / aluminum foil for airtight packing. The nicotine source used will deliver 1.0 mg to 12.6 mg of nicotine per dose i.e. per piece of chewing gum.

[39] Example 3

COMPOSITION OF CHEWING GUM:

The composition of chewing gum is as follows:

Gum base 34% by weight

Plasticizer (propylene glycol or glycerin) 1.5% by weight

Dough forming medium (maltitol syrup) 15.0% by weight

Nicotine source 3.2% by weight

Filler (powdered D-Sorbitol) 35% by weight

Betel nut powder (45 μ m to 710 μ m) 5% by weight

Sweetening agent (Mannitol or any other material providing required sweetness)
5.55% by weight

Peppermint 0.75% by weight and / or other flavoring and mixing the composition thoroughly.

PREPARATION OF CHEWING GUM:

[40] To prepare the chewing of this composition the following process is followed:

- i) mixing chewing gum base, plasticizer, dough forming medium, a portion of filler, betel nut powder and sweetening agent;
- ii) heating the above mixture at 55°C to soften the gum base to form a dough;

- iii) adding the nicotine source prepared by the method as described above to the dough and reheating the dough for uniform mixing of the nicotine source in the dough;
- iv) adding peppermint and any other flavoring agent and mixing thoroughly;
- v) gradually adding the remaining portion of filler to obtain the chewing gum mass;
- vi) spreading the said chewing gum mass in the form of a sheet of uniform thickness and cut into rectangular or any other shaped pieces. The cut pieces are wrapped in wax paper / aluminum foil for airtight packing. The nicotine source used will deliver 1.0 mg to 12.6 mg of nicotine per dose i.e. per piece of chewing gum.

[41] Example 4

COMPOSITION OF CHEWING GUM:

The composition of chewing gum is as follows:

Gum base 25.1% by weight

Plasticizer (propylene glycol or glycerin) 1.0% by weight

Dough forming medium (liquid glucose) 20.8% by weight

Nicotine source 3.2% by weight

Filler (powdered sugar) 45.0% by weight

Betel nut powder (45 μ m to 710 μ m) 4.4% by weight

Peppermint 0.5% by weight. and / or any other flavoring agents and mixing the composition thoroughly.

PREPARATION OF CHEWING GUM:

- [42]** To prepare the chewing gum of this composition the following process is followed:

- i) mixing chewing gum base, plasticizer, dough forming medium, a portion of filler, betel nut powder;
- ii) heating the above mixture at 50°C to soften the gum base to form a dough;
- iii) adding the nicotine source prepared by the method as described above to the dough and reheating the dough for uniform mixing of the nicotine source in the dough;
- iv) adding peppermint and any other flavoring agent and mixing thoroughly;
- v) gradually adding the remaining portion of the filler to obtain the chewing gum mass;
- vi) spreading the said chewing gum mass in the form of a sheet of uniform thickness and cut into rectangular or any other shaped pieces. The cut pieces are wrapped in wax paper / aluminum foil for airtight packing. The nicotine source used will deliver 1.0mg to 12.6 mg of nicotine per dose i.e. per piece of chewing gum.

[43] **Example 5**

CHEWING GUM COMPOSITION:

The composition of chewing gum is as follows:

Gum base 25.1% by weight

Plasticizer (propylene glycol or glycerin) 0.5% by weight

Dough forming medium (liquid glucose 20.8% by weight

Nicotine source 3.2% by weight

Filler (powdered sugar) 44.4% by weight

Betel nut powder (45µm to 710µm) 4.4% by weight

Taste enhancer no. 1 (catechu) 1.0% by weight

Sweetening agent (Aspartame or any other material providing required sweetness)
0.1% by weight.

Peppermint 0.5% by weight and/or any other flavoring agents and mixing the composition thoroughly.

PREPARATION OF CHEWING GUM:

[44] To prepare the chewing gum of this composition the following process is followed:

- i) mixing chewing gum base, plasticizer, dough forming medium, taste enhancer no. 1 i.e. catechu, a portion of filler, betel nut powder and sweetening agent;
- ii) heating the above mixture at 45°C to soften the gum base to form a dough;
- iii) adding the nicotine source prepared by the method as described above to the dough and reheating the dough for uniform mixing of the nicotine source in the dough;
- iv) adding peppermint and any other flavoring agent and mixing thoroughly;
- v) gradually adding the remaining portion of the filler to obtain the tobacco chewing gum mass;
- vi) spreading the said chewing gum mass in the form of a sheet of uniform thickness and cut into rectangular or any other shaped pieces. The cut pieces are wrapped in wax paper / aluminum foil for airtight packing. The nicotine source used will deliver 1.0 mg to 12.6 mg of nicotine per dose i.e. per piece of chewing gum.

[45] **Example 6**

COMPOSITION OF CHEWING GUM:

The composition of chewing gum is as follows:

Gum base 25.1% by weight

Plasticizer (propylene glycol or glycerin) 0.5% by weight

Dough forming medium (Maltitol syrup) 20.8% by weight

Nicotine source 3.5% by weight

Filler (powdered sugar) 44.5% by weight

Betel nut powder (45 μ m to 716 μ m) 4.4% by weight

Taste enhancer no. 2 (lime) 0.5% by weight

Peppermint 1.0% by weight and / or any other flavoring agents and mixing the composition thoroughly.

PREPARATION OF CHEWING GUM:

[46] To prepare the chewing gum of this composition the following process is followed:

- i) mixing chewing gum base, plasticizer, dough forming medium, taste enhancer no. 2 i.e. lime, a portion of filler and betel nut powder;
- ii) heating the above mixture at 55°C to soften the gum base to form a dough;
- iii) adding the nicotine source prepared by the method as described above to the dough and reheating the dough for uniform mixing of the nicotine source in the dough;
- iv) adding peppermint and any other flavoring agent and mixing thoroughly;
- v) gradually adding the remaining portion of filler to obtain the chewing gum mass;
- vi) spreading the said chewing gum mass in the form of a sheet of uniform thickness and cut into rectangular or any other shaped pieces. The cut pieces are wrapped in wax paper / aluminum foil for airtight packing. The nicotine source used will deliver 1.0 mg to 12.6 mg of nicotine per dose i.e. per piece of chewing gum.

[47] Example 7

COMPOSITION OF CHEWING GUM:

The composition of chewing gum is as follows:

Gum base 34.0% by weight

Dough forming medium (liquid glucose) 18.2% by weight

Nicotine source 3.2% by weight

Filler (powdered sugar) 32.9% by weight

Betel nut powder (45µm to 710µm) 4.4% by weight

Taste enhancer no. 1(catechu) 1.0% by weight

Taste enhancer no. 2(lime) 0.5% by weight

Sweetening agent (Mannitol or any other material providing required sweetness)
5.55% by weight

Peppermint 0.5% by weight and / or other flavoring and mixing the composition thoroughly.

PREPARATION OF CHEWING GUM:

[48] To prepare the chewing of this composition the following process is followed:

- i) mixing chewing gum base, dough forming medium, taste enhancer no. 1 i.e. catechu and taste enhancer no. 2 i.e. lime, a portion of filler, betel nut powder and sweetening agent;
- ii) heating the above mixture at 55°C to soften the gum base to form a dough;
- iii) adding the nicotine source prepared by the method as described above to the dough and reheating the dough for uniform mixing of the nicotine source in the dough;
- iv) adding peppermint and any other flavoring agent and mixing thoroughly;
- v) gradually adding the remaining portion of filler to obtain the chewing gum mass;
- vi) spreading the said chewing gum mass in the form of a sheet of uniform thickness and cut into rectangular or any other shaped pieces. The cut

pieces are wrapped in wax paper / aluminum foil for airtight packing. The nicotine source used will deliver 1.0 mg to 12.6 mg of nicotine per dose i.e. per piece of chewing gum.

- [49] To make an evaluation of the product according to the present invention chewing gum prepared by the process of examples 1, 2, 3, 4, 5, 6 and 7 a control sample A was prepared by the method as follows:

20.8 gm of chewing gum base, 20.8 gm of liquid glucose, 24.55 gm of powdered sugar and 4.4 gm of betel nut powder are mixed together, and the mixture is heated at 65°C to soften the gum base to form dough;

4.4gm of quimam is added to the dough and reheating the dough for uniform mixing of the quimam and dough;

0.5 gm of peppermint is added and mixed thoroughly; and

a further amount of 24.55 gm of powdered sugar is added gradually to the mixture to obtain the chewing gum mass.

- [50] The chewing gum mass in the form of a sheet of uniform thickness is cut into rectangular or any other shaped pieces. The cut pieces are wrapped in wax paper / aluminum foil for airtight packing.

- [51] The evaluation was made taking the factors of product smoothness, saliva generation per dose, lingering effect, nicotine intake /day, chewing property, overall taste. A panel of 10 nicotine consumers with intake of nicotine between 70 to 105 mg of nicotine per day divided into 10 to 12 doses through various nicotine containing products other than smoking were used for the purpose of evaluation.

- [52] The chewing gum of the present invention as in examples 1, 2, 3, 4, 5, 6 and 7 are compared with the control example A for the following attributes:

| | ATTRIBUTES | EXAMPLE 1 | EXAMPLE 2 | EXAMPLE 3 | EXAMPLE 4 | EXAMPLE 5 | EXAMPLE 6 | EXAMPLE 7 | EXAMPLE A |
|---|-----------------------|-------------|------------|-------------|-------------|-------------|-------------|-------------|------------|
| 1 | PRODUCT SMOOTHNESS | 90 | 78 | 87 | 84 | 92 | 75 | 92 | 60 |
| 2 | SALIVA GENERATION | 8.0 cc | 9.0 cc | 10.0cc | 10.0 cc | 7.5cc | 6.8 cc | 7.0 cc | 15.0 cc |
| 3 | LINGERING EFFECT | 120 MINUTES | 95 MINUTES | 110 MINUTES | 110 MINUTES | 125 MINUTES | 125 MINUTES | 135 MINUTES | 90 MINUTES |
| 4 | NICOTINE INTAKE / DAY | 52.5 mg | 61.9 mg | 57.3 mg | 58.7mg | 49.9 mg | 49.9 mg | 46.2 mg | 70.0 mg |
| 5 | CHEWING PROPERTY | 8.3 | 7.95 | 8.1 | 8.15 | 8.8 | 8.2 | 8.5 | 7.9 |
| 6 | OVERALL TASTE | 8.2 | 8.4 | 8.6 | 8.75 | 9.0 | 7.9 | 9.2 | 8.15 |

[53] PRODUCT SMOOTHNESS

1- Product Smoothness is an attribute that is related to the degree at which the nicotine is absorbed into the system giving the user the feel. On a scale of 100, example 1 delivers a smoothness of 90, example 2 a smoothness of 78, example 3, 4, 5, 6, and 7 delivers a smoothness of 87, 84, 92, 75, and 92 respectively which is much higher than that delivered by control example A, which delivers a smoothness of 60. Thus the gum based product with nicotine source without taste enhancer is better in respect of this attribute to that with quimam while that with both taste enhancers gives the best result.

[54] SALIVA GENERATION

2- Saliva Generation is the saliva formed during intake of the chewing gum. Example 1 leads to saliva generation of 8.0 cc, examples 2 to 7 saliva generate 9 cc, 10 cc, 10 cc 7.5 cc, 6.8 cc and 7.0 cc, which are much lower than that by control example A which is 15.0 cc. Hence there is less saliva generation in the product with nicotine source without taste enhancer while those with both taste enhancers lead to least saliva generation.

[55] LINGERING EFFECT

3- The lingering effect is the time interval when the user feels the urge to take another dose of nicotine product. The effect of the chewing gum lingers for 120 minutes in example 1, 95 minutes for example 2, 110 minutes for example 3 and 4, 125 minutes for examples 5 and 6, 135 minutes for example 7, which are much higher than the control example A where effect lingers for only 90 minutes.

[56] The lingering effect being higher for the examples 1, 2, 3, 4, 5, 6, and 7 the intake of chewing gum and in the effect nicotine intake per day are less than the control example A. The values of nicotine intake/day being 52.5 mg in example 1, 61.9mg in example 2, 57.3 mg in example 3, 58.7 mg in example 4, 49.9mg in examples 5 and 6, 46.2 mg in example 7, while it is 70 mg in example A.

CHEWING PROPERTY & OVERALL TASTE

[57] Chewing property and overall taste were determined in a scale of 10. Example 1 to 7 revealed values 8.3, 7.95, 8.1, 8.15, 8.8, 8.2 and 8.5 respectively as against 7.9 for example A with respect to Chewing property whereas for Overall Taste the values were 8.2, 8.4, 8.6, 8.75, 9.0, 7.9 and 9.2 for examples 1 to 7 as against 8.15 for example A.

[58] Thus considering all aspects of the experiments done, it is found that betel nut containing chewing gum with nicotine source of the present invention is superior to the control sample. The chewing gum with nicotine source along with both taste enhancers namely catechu and lime, gives a better result than the gum without taste enhancers with respect of the attributes tested.

[59] The gum-based product of the present invention may be used for other applications by incorporating appropriate actives such as caffeine and other alkaloids together with suitable additives.